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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,078	10/29/2003	Cynthia B. Robinson	02486.0065.NPUS01	9187

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,078	ROBINSON ET AL.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election of group I, claims 1-14 without traverse in the reply filed on 3/6/2007 is acknowledged. Applicants' have elected the following species with traverse (received in the office on 5/4/2007). 1) non-glucocorticoid steroids---dehydroepiandrosterone-sulfate (DHEA-S) 2) β2 agonist bronchodilator ----fomoterol 3) Ubiquinone--formula (II) claim 6, n=I 0. Claims 1-14 are pending.

Response to Remarks

Applicants' have argued that non-elected species would not require a burdensome search. In response, the instant application contains claims are directed to the following patentably distinct species: the species of non-glucocorticoid steroids; the species of PDE-4 inhibitors; the species of ubiquinones; The species of non-glucocorticoid steroids, PDE-4 inhibitors, and ubiquinones are independent or distinct because they are different chemical compounds with different structures, chemical and physical properties, bioavailabilities, pharmacokinetic profiles, and pharmacological efficacy. Because the species have different structures and properties, different searches are required for each species, which presents a substantial burden to the Office. The restriction requirement is made final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/923,555. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the pending application teach a pharmaceutical composition comprising the first active agent which is one of non-glucocorticoid steroid and a second active agent which is $\beta 2$ agonist bronchodilator. The instant application teaches non-glucocorticoid steroid species encompassed by the genus non-glucocorticoid steroid compounds taught by the co-pending application. The claims (1-14) of the instant application fall within the scope of the claims 1-15 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Nyce (US 2005/0070487, effective filing date Apr 24 2001).

Nyce teach pharmaceutical composition comprising a first agent selected from a non-glucocorticoid steroid or analogues, or salts such as DHEA or DHEA-S and ubiquinone and a second agent $\beta 2$ agonist, formoterol in a method of treatment of respiratory, lung disorder that include chronic obstructive pulmonary disease, chronic bronchitis, bronchoconstriction, respiratory tract inflammation etc (p 23, claims 58, 59, 76, 80). The reference teach non-glucocorticoid steroid of formula I (para 0035) wherein R1 of formula I is hydrogen or SO2OM, wherein M comprises H, Na, sulfatide etc (para 0036). The reference further teaches that the composition includes ubiquinone of formula II (elected species) or salt thereof, and a pharmaceutically acceptable carrier (para 0042, 0049). The reference further teaches that the compositions can be administered by generating an aerosol or spray comprised of respirable, inhalable, nasal or intrapulmonary delivered particles ranging from 10 to about 100 u in size (p 22, claims 41-46). The reference further teaches a kit comprising such formulation and a delivery device, comprising an inhaler wherein the formulation comprises an inhalable, respirable, intrapulmonary or nasal formulation and the inhaler comprises a nebulizer or insufflator that delivers individual premetered doses of the formulation (p 23, claims 50-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyce (2002/0032160) in view of Jerussi et al. (US 2001/0007679, effective filing date, May 10 1999).

Nyce teach a composition and various formulations comprising therapeutic amounts of non-glucocorticoid steroid of formula I (para 0018) wherein R1 of formula I is hydrogen or SO2OM, wherein M comprises H, Na, sulfatide etc (para 0019). The reference further teaches that the composition includes the compounds of formula I such as DHEA, analogue thereof or salt thereof such as dihydroepidandrosterone sulfate, and/or a ubiquinone of formula II (elected species) or salt thereof, and a pharmaceutically or veterinarily acceptable carrier or diluent that are useful for treating bronchoconstriction, respiratory tract inflammation, allergies, asthma etc (see Abstract, para 0023, p 7, claim 1, p 8, claims 2-7, 11 and 14, p 9, claim 52). The reference further teaches that the compositions can be administered by generating an aerosol or spray comprised of respirable, inhalable, nasal or intrapulmonary delivered particles ranging from 10 to about 100 u in size (p 8, claims 35, 37, 39). The reference further teaches a kit comprising such formulation and a delivery device, comprising an inhaler wherein the

formulation comprises an inhalable, respirable, intrapulmonary or nasal formulation and the inhaler comprises a nebulizer or insufflator that delivers individual premetered doses of the formulation (p 9, claims 42, 43-47).

The reference does not teach a second agent $\beta 2$ agonist bronchodilator in the composition.

Jerrusi et al. teach a method and composition comprising formoterol, a bronchodilator with reduced adverse effects and a convenient and safe formulation for aerosol administration in the treatment of bronchoconstriction, reversible pulmonary disorders etc. (see Abstract, p 8, claims 1, 6)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a second agent $\beta 2$ agonist bronchodilator in a composition comprising DHEA and ubiquinone. The motivation to do so is provided by Jerrusi et al. Jerrusi et al. teach a pharmaceutical composition comprising formoterol, a $\beta 2$ agonist bronchodilator to be useful in the treatment of alleviating airways obstruction, e.g. asthma attack and a composition that has reduced adverse effects and a convenient and safe formulation for aerosol administration. One of ordinary skill in the art would have been motivated to add $\beta 2$ agonist bronchodilator such as formoterol to a composition comprising DHEA and ubiquinone in the treatment of a respiratory condition such as asthma because prior art teaches both the compositions to be useful in the treatment of asthma and one can expect success in achieving a pharmaceutical composition comprising all the three components (a non-glucocorticoid steroid, DHEA sulfate and a $\beta 2$ agonist bronchodilator such as formoterol) and further can expect additive or synergistic effects

in the combination therapy of asthma. The examiner respectfully points out the following from MPEP 2144.06: "It is **prima facie obvious** to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their, having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069,-1072 (CCPA 1980).

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER